

**REMARKS**

Reconsideration and the timely allowance of the pending claims, in view of the following remarks, are respectfully requested.

In the pending Office Action, the Examiner rejected claims 8-12 under 35 U.S.C. § 102(b) as being unpatentable over the '421 patent to Brice, and rejected claims 2-7 under 35 U.S.C. § 103(a) as being unpatentable over the '421 patent in view of the '510 patent to Lamond et al.

Prior to the entry of this Amendment, claims 2-12 were submitted for examination. By this Amendment, Applicant has presented new claims 13-16, all of the which find support in the Specification as filed. Accordingly, claims 2-16 are submitted for examination, of which claims 1, 10 and 13-16 are independent.

Applicant respectfully traverses the rejections under 35 U.S.C. §§ 102(b), and 103(a) for at least the reasons presented herein.

By way of introduction, Applicant respectfully submits that the complexities involved to at least approach full contour-adaptivity of a toothbrush requires that the exact and critical forces, resistances and resiliencies be determined and understood to accomplish full “functioning” of the toothbrush.

Full and complete “functioning” of a toothbrush has not been possible as the forces and resistances demand exactness in terms of describing, specifying and understanding and, further, the dynamic-interaction between a user and the toothbrush is not vague, but an exact science—the prior art merely state that a handle and/or other parts of a toothbrush are “resilient.” To simply state that parts of a prior toothbrush are “resilient” does not really say anything as to the requirements necessary to provide

**BRICE -- Appln. No.: 09/596,081**

understanding as to resistance and to what degree and what force of resilience. For example, a giant oak tree is resilient when faced with a 190 mile-per-hour hurricane wind force but, is resistant to forces below 70 miles-per-hour; how then can one say that without hurricane force winds, this oak tree is resilient at all? This is exactly the problem with known prior art, which simply state one or more parts of a toothbrush as resilient. Without the hurricane force winds of every 100 years or so, the giant oak tree is “immovable” to all considering such stately oak that represents solidity and stability; not so, when the hurricane force winds occur, then such “immovable” oak provides for all witnessing its resiliency. Therefore, one cannot produce functionality with a single-headed toothbrush or otherwise without the full and complete specific knowledge, the full and complete comprehension and the full and exact understanding of what the forces, resiliency and resistances impacting on what specific elements are that allow and/or hinder the dynamic functioning of a toothbrush.

This is the essence: the full and complete comprehension of the forces, resistances and resiliencies specifically involved in the differing elements in response to the specific brushing force of the user to at least approach complete and full contour-adaptivity of twin-brushing heads.

Three examples of such ‘knowledge’ failure were presented to the Examiner at the interview discussing parent Application No. 09/596,081 (“the ‘081 application”). These examples were the Colgate “Navigator” toothbrush, the Crest “Triple-Effect” toothbrush and the Aquafresh “Direct” toothbrush. All three are single-headed toothbrushes with plastic resilient rubber elements incorporated into the heads of each toothbrush, attempting to make such heads ‘movable’ and/or ‘resilient’ when in use and

attempting to achieve some degree of contour following adaptivity. As explained to the Examiner, however, each toothbrush provided material deficiencies disabling them from achieving any real time/real life contour following adaptivity in use.

These material deficiencies are derived from the producers, designers, and engineers lack of knowledge and understanding of the forces, resistances, and resiliency requirements necessary to accomplish such formidable task(s). All three toothbrushes are of a single-headed platform design which, by virtue of its simplicity, demonstrates the critical difficulties of even producing a single-headed toothbrush that functions; let alone, the province of a toothbrush incorporating twin-moving-contour-adaptive heads which force one to enter a far more complicated realm as to the understanding necessary of all forces, resistances, and resiliencies involved.

One can appreciate an embodiment of the invention from the standpoint of the definition of a machine having moving parts, where the force and/or energy of the user is harnessed (the power source). The moving parts of the embodiment of the invention are wholly dependent upon the exact understanding of the degree of force over a range of user variants and what is required to resist such force and at what point or value of such force in which such resistances incorporated into a toothbrush become resilient. Full functioning of this toothbrush is not possible without this knowledge and the lack of such knowledge prevents any possibility on the part of this toothbrush or any other(s) from realizing dynamic contour-adaptivity that provides workability and functionality for the user. Therefore, merely stating that a device is resilient does not provide any degree of knowledge as to what is required on the part of the device to "function" in the real world of products "in use."

Accordingly, those skilled-in-the-art did not possess the requisite understanding and/or ability(ies) required to achieve what one embodiment of the invention provides, in terms of exact and explicit understanding, required for accomplishing contour-adaptivity of a moving and/or active device powered by the user.

The '421 patent states certain concepts and/or considerations relative to energy retention and release. The '421 patent states that

The force/energy transmitted by the user to the handle thereby transmitted to the neck portion and separate heads of the invention encounter resistance, thereby increasing the accumulation of energy in the material composition of the handle and heads. This energy is released when the differing resistance areas are passed over and the "release" is realized in the "spring action" of the two heads.

However, no degree of spring-action is stated, nothing of achieving full contour adaptivity and of achieving contact with the dento-gingival junction.

Also, the '421 patent states that

Through understanding and addressing the dynamic interaction between the user and device and utilizing the material characteristics of the common material used in the manufacture and construction of toothbrush devices.

However, the passage is non-specific, further indicated as the "understanding of retention and release of energy." The '421 patent states nothing about specifying necks and/or uniform bristle body mass offering resistance and then providing resiliency as to a force as may be applied—it just states the retention and release of energy.

The '421 patent merely states a general appreciation for the 'accumulation and release' of such energy in such material composition. While it is accurate that energy is stored and then released these statements in no way show any appreciation for (1) the value of such force, (2) the necessity to provide resistance to the force by the flexible

neck portions of the toothbrush to the degree that such necks resist such force and then become resilient to such force based upon the resistance/resiliency characteristics of the neck structures meeting obstructions and (3) upon such resistance of such separate and combined neck structures do they provide contour-adaptivity only by being directly related to the resistance and resiliency characteristics of the twin-bristle body heads and the exact determinations of their resistance/resiliency related to the neck structures all combined corresponding to the force(s) exerted by the user.

The '421 patent states that "The bristle body heads of the present invention encounter resistance from the changing curvilinear structures encountered during brushing." The '421 patent, however, does not state that the bristle body heads provide resistance to the changing curvilinear structures encountered during brushing—herein lies at least one material difference between the '421 patent and the present invention. Additionally, the '421 patent only states that they (the neck structures and brushing heads) "encounter resistance" and not that they act resistant to such curvilinear structures encountered during brushing. This is altogether different worlds and completely different considerations than the present invention.

Therefore, it can be appreciated that the '421 patent is addressing elements completely different than what are the issues and considerations addressed in the present invention. On the surface, it appears that they share similarities, however, on closer examination, one discovers that completely different issues and considerations are at work here and the '421 patent, describing and considering elements unrelated to the province of this invention.

The '081 application also addresses providing orientation and access to the 'dento-gingival junction' of the user's tooth/teeth and gum structure with the inside and outside rows of such twin-headed toothbrush. Without the understanding of this invention, such orientation and access to such regions may be impossible because without actual functioning contour-adaptivity, optimum cleaning of such regions is limited and restricted to lack of contour-adaptivity and consequently, access and contact with all surfaces encountered during brushing is incomplete and not sufficiently realized. This is the cost of not considering in exact terms the elements of a toothbrush.

One purpose of such efforts is to produce contact with all regions encountered during brushing and without the elements of the invention, any effort is incomplete and, since proper removal of bacterial plaque is a public health and personal medical issue, the importance of this application cannot be overstated.

The studies and results described in the attached scientific document were conducted by Professor Hubert N. Newman; Director, Oral Health Research Center, N.W. London Community Dental Services; London, United Kingdom. The document describes the clinical trials that were conducted utilizing a toothbrush described and claimed in this application. Also, the described clinical studies were published and presented at the 81<sup>st</sup> General Session of the International Association of Dental Research; at Gottenborg, Sweden on June 26, 2003. As explained in the attached document under the "Discussion" section:

The present study demonstrated that the XTRA Clinical Toothbrush™ was significantly more effective than the Oral B CrossAction® toothbrush in removing supragingival plaque.

1. Rejection Under 35 U.S.C. § 102

A. Claims 8-12

Claims 8-12 were rejected under 35 U.S.C. § 102(b) as being anticipated by the '421 patent. The Examiner reported that FIG. 10 of the '421 patent "discloses all of the structure claimed." The Examiner also reported that the "wherein" phrases at the end of Applicant's claims 9-12 do "not define any particular relationship" and "do not appear to define any structure." The Examiner further reported that "[m]erely claiming that various components of the toothbrush are designed, one part [necks] being 'set' with respect to another part [bristles], to brush well does not appear to distinguish from the '421 patent." In addition, the Examiner reported that bristles of the '421 patent "will" have a stiffness and the necks of the '421 patent "will" have a resiliency, flexibility and bending resistance "as is claimed." Applicant respectfully traverses the rejection.

1) Claims 8-10

Applicant's independent claim 10 claims a toothbrush requiring: a handle; necks coupled to the handle; bristle supports coupled to the necks; and bristles coupled to the bristle supports, wherein a resiliency, flexibility and bending resistance of the claimed necks are set depending upon both (i) a brushing force and (ii) a stiffness of the claimed bristles, such that the toothbrush, through the bristles coupled to the necks, adapts to a }  
dento-gingival junction and all other changing surfaces encountered during brushing to  
disrupt plaque. Clearly, the "wherein" phrase at the end of claim 10 recites features of the  
claimed necks and, as such, further defines the claimed toothbrush. See, e.g., In re  
Swinehart, 439 F.2d 210, 212 (CCPA 1971) ("There is nothing intrinsically wrong with  
[defining something by what it does rather than what it is] in drafting patent claims.").

In comparison, the Examiner reported that the '421 patent discloses a toothbrush with bristles that will have a stiffness and necks that will have a resiliency, flexibility and bending resistance "as is claimed." The Examiner, however, did not cite where in the description of the '421 patent necks, configured to have a resiliency, flexibility and bending resistance that are set depending upon both (i) a brushing force and (ii) a stiffness of bristles, such that a toothbrush, through the bristles coupled to the necks, adapts to a dento-gingival junction and all other changing surfaces encountered during brushing to disrupt plaque, are disclosed. Applicant respectfully submits that the Examiner has misread the '421 patent, among other things, because the '421 patent does not disclose (expressly or inherently) the necks as claimed. The Examiner's omission of a specific cite to support his position reflects that the '421 patent has no such disclosure.

One physical difference between the toothbrush of claim 10 and the toothbrush of FIG. 10 of the '421 patent is that the toothbrush of claim 10, unlike the toothbrush of the '421 patent, is configured to carry out the features of the "wherein" phrase at the end of claim 10 creating a new toothbrush, because it becomes a special toothbrush once it is configured to perform the claimed features. Cf. In re Bernhart, 417 F.2d 1395, 1399-1400 (CCPA 1969) ("if a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program").

Also, the toothbrush of the '421 patent does not adapt to a dento-gingival junction and all other changing surfaces encountered during brushing to disrupt plaque, since its necks are not configured to have a resiliency, flexibility and bending resistance that are set depending upon both (i) a brushing force and (ii) a stiffness of its bristles.



Thus, Applicant respectfully submits that claim 10, which requires a resiliency, flexibility, and bending resistance of the necks to be set depending upon a brushing force and a stiffness of the bristles, is clearly not anticipated by the '421 patent. Applicant respectfully submits that the '421 patent fails to teach all the structure recited in the rejected independent claim, as well as its dependent claims, and therefore cannot be construed as anticipating the claimed invention. Moreover, the '421 patent includes no suggestion for modifying its necks as to change their configurations to include the claimed features, and therefore cannot be construed as rendering obvious the claimed invention. As such, Applicant respectfully requests that the rejection of claims 8-10 under 35 U.S.C. § 102 be withdrawn. Independent claim 1 is allowable. In addition, its dependent claims are allowable for reasons of their dependencies, as well as their additional limitations. For example, claim 9 requires that the resiliency, flexibility and bending resistance of the necks and the bristle supports to be set depending upon both (i) the brushing force and (ii) the stiffness of the bristles.

2. Claims 11-12

Applicant's independent claim 11 claims a toothbrush requiring: a handle; necks coupled to the handle; bristle supports coupled to the necks; and bristles coupled to the bristle supports, wherein a stiffness of the claimed bristles is set depending upon both (i) a brushing force and (ii) a resiliency, flexibility and bending resistance of the claimed necks, such that the toothbrush, through the bristles coupled to the necks, adapts to a dento-gingival junction and all other changing surfaces encountered during brushing to disrupt plaque. Clearly, the "wherein" phrase at the end of claim 11 recites features of the claimed bristles and, as such, further defines the claimed toothbrush. See, e.g., In re

Swinehart, 439 F.2d 210, 212 (CCPA 1971) (“There is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims.”).

In comparison, the Examiner reported that the ‘421 patent discloses a toothbrush with bristles that will have a stiffness and necks that will have a resiliency, flexibility and bending resistance “as is claimed.” The Examiner, however, did not cite where in the description of the ‘421 patent bristles, configured to have a stiffness that is set depending upon both (i) a brushing force and (ii) a resiliency, flexibility and bending resistance of the claimed necks, such that the toothbrush, through the bristles coupled to the necks, adapts to a dento-gingival junction and all other changing surfaces encountered during brushing to disrupt plaque, are disclosed. Applicant respectfully submits that the Examiner has misread the ‘421 patent, among other things, because the ‘421 patent does not disclose (expressly or inherently) the bristles as claimed. The Examiner’s omission of a specific cite to support his position reflects that the ‘421 patent has no such disclosure.

One physical difference between the toothbrush of claim 11 and the toothbrush of FIG. 10 of the ‘421 patent is that the toothbrush of claim 11, unlike the toothbrush of the ‘421 patent, is configured to carry out the features of the “wherein” phrase at the end of claim 11 creating a new toothbrush, because it becomes a special toothbrush once it is configured to perform the claimed features. Cf. In re Bernhart, 417 F.2d 1395, 1399-1400 (CCPA 1969) (“if a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program”).

Also, the toothbrush of the ‘421 patent does not adapt to a dento-gingival junction and all other changing surfaces encountered during brushing to disrupt plaque, since its

**BRICE** -- Appln. No.: 09/596,081

bristles are not configured to have a stiffness that is set depending upon both (i) a brushing force and (ii) a resiliency, flexibility and bending resistance of its necks.

Thus, Applicant respectfully submits that claim 11, which requires the stiffness of the bristles to be set depending upon a brushing force and a resiliency, flexibility and bending resistance of the necks, is clearly not anticipated by the '421 patent. Applicant respectfully submits that the '421 patent fails to teach all the structure recited in the independent claim, as well as its dependent claim, and therefore cannot be construed as anticipating the claimed invention. Moreover, the '421 patent includes no suggestion for modifying its bristles as to change their configurations to include the claimed features, and therefore cannot be construed as rendering obvious the claimed invention. As such, independent claim 10 is allowable. In addition, its dependent claim is allowable for reasons of its dependency, as well as its additional limitations. For example, claim 11 requires that the stiffness of the bristles to be set depending upon both (i) the brushing force and (ii) the resiliency, flexibility and bending resistance of the necks and the bristle supports.

2. Rejection Under 35 U.S.C. § 103

Claims 2-7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the '421 patent in view of the '510 patent. Applicant respectfully traverses the rejection. Claims 2-7 are depended upon independent claim 10. As noted above, independent claim 10 has been shown to be allowable. As such, Applicant respectfully requests that the rejection of claims 2-7 under 35 U.S.C. § 103(a) be withdrawn. Claims 2-7 are allowable for reasons of their dependencies, as well as their additional limitations.

**BRICE -- Appln. No.: 09/596,081**

3. Conclusion

In view of the above, claims 2-16 are believed to be in form for allowance, and such an action is hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, he is requested to telephone the undersigned at the number below.

Respectfully submitted,

PATTON BOGGS LLP

By

  
Joseph V. Colajanni

Reg. No.: 20,019

Tel. No.: (202) 457-6174

Fax No.: (202) 457-6315

JVC/WGB

2550 M Street, N.W.  
Washington, D.C. 20037  
(202) 457-6000  
Enclosure: Appendix

## Introduction

Dental plaque is considered to be the primary factor associated with both dental caries and gingival inflammation. Mechanical removal of plaque by toothbrushing is dependent on the skills, perseverance and motivation of the individual and is therefore highly variable and inconsistent in the general population. A previous study<sup>1</sup> demonstrated that the XTRA Clinical toothbrush<sup>2</sup> was comparable to the Oral B CrossAction toothbrush and superior to the Oral B Advantage toothbrush in removing supragingival plaque. The purpose of this study was to compare the ability of two prototypes of the XTRA Clinical toothbrush, one with increased bristle angulation (X1), and the other with the original bristle angulation but reduced bristle length (X2), with that of the Oral B CrossAction toothbrush.

## Aims

The aim of this single-blind, crossover study was to compare the performance of two prototypes of the twin-headed toothbrush (New Millennium XTRA Clinical), one with the bristle angulation increased (X1), and the other with the original bristle angulation but reduced bristle length (X2), to remove supragingival plaque compared with that of the Oral B CrossAction toothbrush.

## Method

The volunteers, after informed, written consent, were given a dental prophylaxis to remove all clinically apparent hard and soft deposits on the teeth. They were then given one of the test toothbrushes in a randomised order and a tube of Colgate Regular Flavour toothpaste and instructed to use the toothbrush and toothpaste in their normal manner at home in place of their current toothbrush and toothpaste for the following two weeks. They were instructed to refrain from using dental floss and mouthwash during this period. The volunteers returned to the clinic for assessment of plaque and oral soft and hard tissues having abstained from all oral hygiene procedures for 24 hours prior to their appointment. Pre-brushing plaque accumulation was disclosed with FD&C Red#28 dye and assessed by plaque index<sup>3</sup> at six sites per tooth on the buccal and lingual surfaces of the teeth. The volunteers then brushed their teeth with the same toothbrush they had used for the previous two weeks in their usual manner. Post-brushing plaque was disclosed and reassessed. The volunteers repeated the procedures on two further occasions using the other two toothbrushes.

Fig. 1 Test Toothbrushes



Table 1. Demographics of Subjects

Subjects	Age (yr)	Smoker/Non-smoker
Males (n = 5)	34.2 (8.3)	1/4
Females (n = 21)	30.0 (5.0)	8/13
Total (n = 26)	30.9 (6.3)	9/17

Table 2. Brushing Times and Toothpaste Use (s)

Toothbrush	Mean Brushing Time (s)	Mean Toothpaste Use (s)
XTRA Clinical (X1)	2.01 (0.37)	1.49 (0.78)
XTRA Clinical (X2)	2.10 (0.52)	1.52 (1.07)
Oral B CrossAction	2.09 (0.52)	1.70 (1.12)

Table 3. Plaque Index Values (sd)

Toothbrush	Pre-brushing plaque index	Post-brushing plaque index	Plaque removed	% difference
XTRA Clinical (X1)	3.65 (0.38)	1.92 (0.64)	1.73	10.2
Oral B CrossAction	3.51 (0.59)	1.84 (0.66)	1.56	p = 0.08
XTRA Clinical (X2)	3.84 (0.48)	2.08 (0.56)	1.57	0.0
Oral B CrossAction	3.51 (0.59)	1.84 (0.66)	1.56	N.S.
XTRA Clinical (X1)	3.65 (0.38)	1.92 (0.64)	1.73	10.1
XTRA Clinical (X2)	3.84 (0.48)	2.08 (0.56)	1.57	N.S.

## Results

Twenty-six volunteers (5M, 21F) with a mean age 30.8 years (sd = 6.1) completed the study - Table 1. There was no significant difference in the mean brushing time for any of the test toothbrushes or in mean weight of toothpaste used - Table 2.

Brushing with the XTRA Clinical toothbrush with increased bristle angulation (X1) removed significantly more plaque (10.2%; p = 0.03 Wilcoxon Sum of Ranks Test) than brushing with the Oral B CrossAction toothbrush. The difference in plaque removed by the two twin-headed toothbrushes (X1 and X2) was greater (10.1%; NS) for the toothbrush with increase bristle angulation (X1); the difference was not statistically significant. There was no significant difference in plaque removed by the twin-headed toothbrush with shortened bristles (X2) compared with that removed by the Oral B CrossAction toothbrush - Table 3.

## Discussion

Previous studies<sup>4,5</sup> have demonstrated that the Oral B CrossAction toothbrush is significantly more effective in removing plaque than many other toothbrushes. The present study demonstrated that the XTRA Clinical toothbrush was significantly more effective than the Oral B CrossAction toothbrush in removing supragingival plaque.

## Conclusions

It may be concluded that in the absence of formal oral hygiene instruction all of these toothbrushes are effective in removing supragingival plaque. Increasing the angulation of the filaments of the twin-headed XTRA Clinical toothbrush enhanced plaque removal such that significantly more plaque was removed than with the Oral B CrossAction toothbrush.

## References

1. Jackson RJ, Newman HN, Aris A & Farukh R. J Dent Res. (to be published 2003)
2. US Patent Numbers 5,121,520; 5,499,421 & 6,112,361.
3. Turecky S, Gitmore N & Glickman I. J Periodontol. 1970;41:41-43.
4. Cronin MJ, Dembling WZ, Low ML et al. Amer J Dent 2000;13:21A-25A.
5. Sharma NC, Qaqish JG, Galustians HJ et al. Amer J Dent. 2000;13:15A-19A.

Study supported by New Millennium Scientific NMOC, Inc. New York, USA.

Not Available Copy